REMARKS

The February 15, 2007, Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the February 15, 2007 Official Action. Therefore, the initial due date for response is May 15, 2007. This response is being filed within the two month extension period. Accordingly, a petition for a two month extension of time and the requisite fee is also submitted herewith.

The Examiner has maintained the rejection of claims 17-21, 25, 26 and 28 under 35 U.S.C. §101 because the claimed invention is allegedly not supported by a specific, substantial, or a well-established utility. As a result, the Examiner also maintained the rejection of claims 17-21, 25, 26 and 28 under 35 U.S.C. § 112, first paragraph contending that since the invention allegedly lacks utility, one skilled in the art would not know how to use the claimed invention.

Claims 17-21, 25, 26 and 28 have also been rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to satisfy the enablement and written description requirements of the statute.

Lastly, claims 17-20, and 26 stand rejected for allegedly failing to satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

The foregoing rejections constitute all of the grounds set forth in the February 15, 2007, Official Action for refusing the present application. Applicants respectfully

request reconsideration and examination of this application and the timely allowance of the pending claims 17-21, 25, 26 and 28 in view of the claim amendments submitted herewith and the arguments set forth below.

SUMMARY OF INTERVIEW

Applicants would like to thank Examiners Chen and Paras for taking the time to conduct an interview with the undersigned to discuss the various rejections maintained in the Final Official Action.

Specifically, the undersigned emphasized the disclosure in the specification which evidence the clear and credible utility of the transgenic mice encompassed by the present claims. As set forth in the Declaration of Dr. Vidal and the disclosure in the specification, the claimed transgenic mice exhibit aberrant deposition of ferritin and iron in the cells of the central nervous system. See page 11, lines 35 and 36. The mice recapitulate the phenotype observed in humans expressing this FTL variant. As set forth at page 38, lines 6 - 25, "*Transgenic mice expressing the FTL variant of the invention provide a model system in which to examine the role of the FTL variant in the development and progression of neurodegenerative disease…Production of the transgenic mice described above will facilitate the molecular elucidation of the role that a target protein (e.g. FTL) plays in various cellular processes, including the intracellular accumulation of ferritin and/or iron, biochemical pathways involved in iron metabolism and development of degenerative disorders related to aberrant accumulation of intracellular iron, particularly those affecting the nervous system.*"

Applicants contend that the skilled person having this

disclosure before him or her would readily appreciate the utility of the mice as a screening tool to identify agents which modulate ferritin and iron deposition in cells. Inasmuch as the mice do have a credible utility, the skilled person is readily enabled to utilize such mice in screening assays to identify therapeutic agents having efficacy for neurodegenerative disorders associated with aberrant ferritin and iron deposition.

While not agreeing with the Examiner's assertion that the use of all species of transgenic animals expressing the FTL variant of the invention is not adequately described or enabled, in order to expedite prosecution of the present application, during the interview, the undersigned agreed to amend the claims to remove the term animal and replace it with the term mouse. It is submitted that the transgenic mice encompassed by the claims are fully enabled and adequately described in the application as filed.

CLAIMS 17-21, 25, 26 AND 28 AS AMENDED, SATISFY THE REQUIREMENTS OF 35 U.S.C. §§101 and 112, FIRST PARAGRAPH

For the reasons set forth above, Applicants continue to strenuously disagree with the Examiner's assertion that the specification fails to provide any support (Official Action of 2/15/07, line 3) for the phenotype of the claimed transgenic animals. As indicated above, the inventors were confident that the phenotype observed in humans would be recapitulated in transgenic mice and accordingly described and enabled the production of transgenic mice for use as a model in vivo system to identity therapeutic agents which modulate aberrant iron deposition and metabolism observed in certain ferritinopathies. It is submitted that the

skilled artisan in such disorders, having the present specification would know to use the claimed transgenic mice to assess the tissues for the various aberrations described in Figures 2, and 8-17 and then administer test agents to such mice to assess whether they reverse or augment the aberrant iron deposition observed.

At page 6 of the Official Action, the Examiner again asserts that Applicants have not provided a phenotype for the claimed transgenic mice. This assertion is directly contradicted by the disclosure at page 38 set forth above which clearly reflects the inventors appreciation that the transgenic mice would be useful as an in vivo model to study abberant iron and ferritin deposition and the associated neuropathies.

While not agreeing with the Examiner's assertion that the phrase "intranuclear and intracytoplasmic ferritin bodies" in claim 17 comprises new matter, the phrase has been replaced with *"aberrant deposition of ferritin and iron in cells of the central nervous system"*. Literal support for this recitation can be found at page 11, line 34 and at page 38, lines 19-25.

Applicants submit that the inventors did have possession of the transgenic mice of the invention at the time the application was filed. Applicants had possession of the FTL variant sequence. Methods of creating transgenic mice in 2007 are fairly routine. Following the method steps described in the specification, transgenic mice having the features recited in the claims and described at page 38 were produced. It light of the foregoing, it cannot be reasonably maintained that Applicants were not in possession of the invention as of the effective filing date.

For all of the above reasons, it is respectfully urged that the present specification and claims are directed to statutory subject matter and are fully described and enabled. Accordingly, Applicants request that the Examiner withdraw the rejections of the present claims under §§101 and 112, first paragraph. Additionally, Applicants again request rejoinder of claim 22.

CONCLUSION

It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the rejections set forth in the February 15, 2007 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone or

in-person interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
A Professional Corporation

By /Kathleen D. Rigaut/
Kathleen D. Rigaut, Ph.D., J.D.
PTO Registration No. 43,047

Telephone: (215) 563-4100
Facsimile: (215) 563-4044
Email: krigaut@ddhs.com